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(54) Transmyocardial revascularisation device

(57) A method provides a closed-chest formation of a channel in a wall of a heart. A transmyocardial revascularisation energy delivery device is introduced through a first minimally invasive penetration of a patient's chest. Sufficient energy if delivered from the wave guide e.g. by a laser to the wall of the heart to form a channel through at least a portion of the wall. The device comprises a visualization member like a CCD-camera.

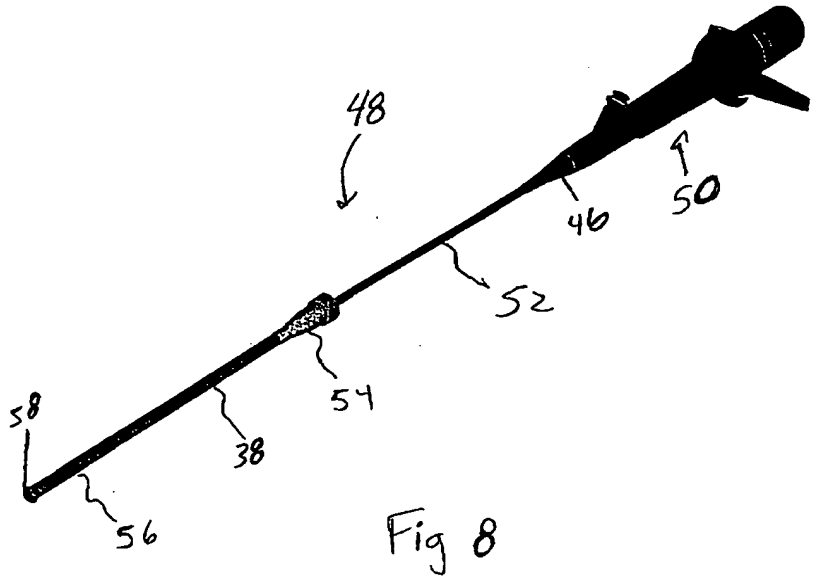

Fig 8

EP 0 858 779 A1

Description

This invention relates to transmyocardial revascularization ("TMR"), and more particularly to a TMR method that introduces an energy delivery device through a minimally invasively formed penetration of a patient's chest.

The human heart is a muscular dual pump that beats continuously throughout life sending blood to the lungs and the rest of the body. The interior of the heart consists of four distinct chambers. The septum, a thick central muscular wall, divides the cavity into right and left halves. On the right side, the upper half is known as the right atrium. Deoxygenated blood from the rest of the body arrives in the right atrium via the vena cava, the blood is pumped across a one-way valve known as the tricuspid valve into the lower portion known as the right ventricle. From there the blood circulates to the lungs through the pulmonary valve via the pulmonary artery where it is oxygenated by circulation through the alveoli of the lungs (not shown). The blood returns via the pulmonary veins to the left atrium and flows through a second valve, the mitral valve into the left ventricle where it is pumped via the aorta to the rest of the body.

Much of the heart consists of a special type of muscle called myocardium. The myocardium requires a constant supply of oxygen and nutrients to allow it to contract and pump blood throughout the vasculature. The inner surfaces of the chambers of the heart are lined with a smooth membrane, the endocardium, and the entire heart is enclosed in a tough, membranous bag known as the pericardial sac.

The pumping action of the heart has three main phases for each heart beat. *Diastole* is the resting phase during which the heart fills with blood: while deoxygenated blood is entering the right atrium, oxygenated blood is returned from the lungs to the left atrium. During *atrial systole*, the two atria contract simultaneously, squeezing the blood into the lower ventricles. Finally, during *ventricular systole* the ventricles contract to pump the deoxygenated blood into the pulmonary arteries and the oxygenated blood into the main aorta. When the heart is empty, *diastole* begins again. The electrical impulses which stimulate the heart to contract in this manner emanate from the heart's own pacemaker, the sinoatrial node. The heart rate is under the external control of the body's *autonomic nervous system*.

Though the heart supplies blood to all other parts of the body, the heart itself has relatively little communication with the oxygenated blood supply. Thus, the two coronary arteries, the left coronary artery and the right coronary artery, arise from the aorta and encircle the heart muscle on either side "like a crown" to supply the heart itself with blood.

Heart disorders are a common cause of death in developed countries. They also impair the quality of life of millions of people and restrict activity by causing pain, breathlessness, fatigue, fainting spells and anxiety. The major cause of heart disease in developed countries is impaired blood supply. The coronary arteries become narrowed due to *atherosclerosis* and part of the heart muscle is deprive of oxygen and other nutrients. The resulting *ischemia* or blockage can lead to *angina pectoris*, a pain in the chest, arms or jaw due to a lack of oxygen to the heart, or *infarction*, death of an area of the myocardium caused by the *ischemia*.

Techniques to supplement the flow of oxygenated blood directly from the left ventricle into the myocardial tissue have included needle acupuncture to create transmural channels (see below) and implantation of T-shaped tubes into the myocardium. Efforts to graft the omentum, parietal pericardium, or mediastinal fat to the surface of the heart had limited success. Others attempted to restore arterial flow by implanting the left internal mammary artery into the myocardium.

Modernly, coronary artery blockage can be relieved in a number of ways. Drug therapy, including nitrates, beta-blockers, and peripheral vasodilator drugs (to dilate the arteries) or thrombolytic drugs (to dissolve clots) can be very effective. If drug treatment fails transluminal angioplasty is often indicated - the narrowed part of the artery, clogged with atherosclerotic plaque or other deposits, can be stretched apart by passing a balloon to the site and gently inflating it a certain degree. In the event drug therapy is ineffective or angioplasty is too risky (often introduction of a balloon in an occluded artery can cause portions of the atherosclerotic material to become dislodged which may cause a total blockage at a point downstream of the subject occlusion, thereby requiring emergency procedures), the procedure known as coronary artery bypass grafting (CABG) may be indicated. CABG is the most common and successful major heart operation performed, with over 500,000 procedures being performed annually in America alone. The procedure takes at least two surgeons and can last up to five hours. First, the surgeon makes an incision down the center of the patient's chest and the heart is exposed by opening the pericardium. A length of vein is removed from another part of the body, typically the leg. The patient is connected to a heart-lung machine which takes over the function of the heart and lungs during the operation. The section of vein is first sewn to the aorta and then sewn onto a coronary artery at a place such that oxygenated blood can flow directly into the heart. The patient is then closed. Not only does the procedure require the installation of the heart-lung machine, a very risky procedure, but the sternum must be sawed through and the risk of infection is enhanced during the time the chest cavity is spread open.

Another method of improving myocardial blood supply is called *transmyocardial revascularization* (hereafter "TMR"), the creation of channels from the epicardial to the endocardial portions of the heart. The procedure uses needles in a form of "myocardial acupuncture," has been experimented with at least as early as the

1930s and used clinically since the 1960s. Deckelbaum. L.I., Cardiovascular Applications of Laser technology, *Lasers in Surgery and Medicine* 15:315-341 (1994). The technique was said to relieve ischemia by allowing blood to pass from the ventricle through the channels either directly into other vessels perforated by the channels or into myocardial sinusoids which connect to the myocardial microcirculation. The procedure has been likened to transforming the human heart into one resembling that of a reptile.

In the reptile heart, perfusion occurs via communicating channels between the left ventricle and the coronary arteries. Frazier, O.H., Myocardial revascularization with Laser - Preliminary Findings, *Circulation*, 1995; 92 [suppl II:II-58-II-65]. There is evidence of these communicating channels in the developing human embryo. In the human heart, myocardial microanatomy involves the presence of myocardial sinusoids. These sinusoidal communications vary in size and structure, but represent a network of direct arterial-luminal, arterial-arterial, arterial-venous, and venous-luminal connections. This vascular mesh forms an important source of myocardial blood supply in reptiles but its role in humans is poorly understood.

Numerous studies have been performed on TMR using lasers to bore holes in the myocardium. The exact mechanism by which blood flows into the myocardium is not well understood however. In one study, 20-30 channels per square centimeter were bored into the left ventricular myocardium of dogs prior to occlusion of the arteries. LAD ligation was conducted on both the revascularized animals as well as a set of control animals. Results showed that animals having undergone TMR prior to LAD ligation acutely showed no evidence of ischemia or infarction in contrast to the control animals. After sacrifice of the animals post operatively between 4 weeks and 5 months, the laser-created channels could be demonstrated grossly and microscopically to be open and free of debris and scarring.

It is believed that the TMR channels occlude toward the epicardial surface but that their subendocardial section remains patent (unobstructed) and establishes camerosinusoidal connections. It is possible that the creation of laser channels in the myocardium may promote long-term changes that could augment myocardial blood flow such as by inducing angiogenesis in the region of the lazed (and thus damaged) myocardium. Support for this possibility is reported in histological evidence of probable new vessel formation adjacent to collagen occluded transmyocardial channels. In the case of myocardial acupuncture or boring, which mechanically displaces or removes tissue, acute thrombosis followed by organization and fibrosis of clots is the principal mechanism of channel closure. By contrast, histological evidence of patent, endothelium-lined tracts within the laser-created channels supports the assumption that the inside of the laser channels is or can become hemocompatible and that it resists occlusion caused by thrombo-activation and/or fibrosis. A thin zone of charring occurs on the periphery of the laser-created transmyocardial channels through the well-known thermal effects of optical radiation on cardiovascular tissue. This type of interface may inhibit the immediate activation of the intrinsic clotting mechanisms because of the inherent hemocompatibility of carbon. In addition, the precise cutting action that results from the high absorption and low scattering of laser energy (CO_2, HO, etc.) may minimize structural damage to collateral tissue, thus limiting the tissue thromboplastin-mediated activation of the extrinsic coagulation.

U.S. Patent No. 4,658,817 issued Apr. 21, 1987 to Hardy teaches a method and apparatus for TMR using a laser. A surgical CO_2 laser includes a handpiece for directing a laser beam to a desired location. Mounted on the forward end of the handpiece is a hollow needle to be used in surgical applications where the needle perforated a portion of tissue to provide the laser beam direct access to distal tissue.

U.S. Patent No. 5,125,926 issued Jun. 30, 1992 to Rudko et al. teaches a heart-synchronized pulsed laser system for surgical TMR. The device and method comprises a device for sensing the contraction and expansion of a beating heart. As the heart beat is monitored, the device triggers a pulse of laser energy to be delivered to the heart during a predetermined portion of the heartbeat cycle. This heart-synchronized pulsed laser system is important where the type of laser, the energy and pulse rate are potentially damaging to the beating heart or its action. Often, application of laser energy to a beating heart can induce fibrillation or arrhythmia. Additionally, as the heart beats, its spatial relationship between the heart and the tip of the laser delivery probe may change so that the necessary power of the beam and the required position of the handpiece may be unpredictable.

Finally, U.S. Patent Nos. 5,380,316 issued Jan. 10, 1995 and 5, 389,096 issued Feb. 14, 1995 both to Aita et al. teach systems and methods for intra-operative and percutaneous myocardial revascularization, respectively. The former patent is related to TMR performed by inserting a portion of an elongated flexible lasing apparatus into the chest cavity of a patient and lasing channels directly through the outer surface of the epicardium into the myocardium tissue. In the latter, TMR is performed by guiding an elongated flexible lasing apparatus into a patient's vasculature such that the firing end of the apparatus is adjacent the endocardium and lases channels directly through the endocardium into the myocardium tissue without perforating the pericardium layer. None of the above patents teach any method for performing TMR in a minimally invasive surgical procedure, nor do they teach methods of visualizing the areas of the heart being lazed, nor do they teach any method or devices for achieving TMR on surfaces or portions of the heart which are not directly accessible via a sternotomy, mini-sternotomy or via a trocar.

There is a need for a method and apparatus for performing TMR with one or more minimally invasively formed penetrations and eliminating the need for opening the chest cavity.

Accordingly, an object of the invention is to provide a method and apparatus for performing TMR.

Embodiments of the invention desirably provide one or more of the following:

a method and apparatus for minimally invasively performing TMR;
a method and apparatus for performing TMR through a minimally invasively formed penetration of a patient's chest;
a method and apparatus for performing TMR through a single minimally invasively formed penetration of a patient's chest;
a method and apparatus for performing TMR through two minimally invasively formed penetrations of a patient's chest;
a method and apparatus for performing TMR through three minimally invasively formed penetrations of a patient's chest;
a method and apparatus for performing TMR through a minimally invasively formed penetration in a patient's chest with an articulating scope that includes at least one working channel;
a method and apparatus for TMR through first and second minimally invasively formed penetrations in a patient's chest with an articulating scope in the first penetration and a trocar configured to introduce working tools through the second penetration;
a method and apparatus for TMR by forming one or more minimally invasively formed penetrations and to provide access to more than one region of the heart.

Embodiments of apparatus according to the present invention may be used in a method for a closed-chest formation of a channel in a wall of a heart. An energy delivery device is introduced through a first minimally invasive penetration of a patient's chest. Sufficient energy is delivered from the energy delivery device to the wall of the heart to form a channel through at least a portion of the wall. Preferably, the method further comprises viewing at least a portion of an interior of the patient's chest, at least prior to delivering energy from the TMR energy delivery device. In its simplest embodiment, a conventional pneumo needle may be inserted through the chest wall and a laser waveguide inserted therethrough to form a channel, preferably using a viewing apparatus to show the position of the advancing waveguide and the heart wall.

In one embodiment of the invention a method of closed-chest formation of a channel in a wall of a heart includes introducing a first visualization apparatus through a first minimally invasive penetration of a patient's chest and introducing the TMR energy delivery device through the visualization apparatus. For instance, the first visualization apparatus includes a working channel. An energy delivery device is introduced through the working channel of the first visualization device. Sufficient energy is delivered from the energy delivery device to the wall of the heart to form a channel through at least a portion of the wall.

Preferred embodiments of the aforementioned methods comprise one or more of the following:

(a) forming a second minimally invasive penetration of the patient's chest; and introducing a tool through a second minimally invasive penetration;

(b) introducing a tool through a third minimally invasive penetration of the patient's chest;

(c) at least partially collapsing a lung of the patient;

(d) positioning a distal portion of the TMR energy delivery device to reach a desired aspect of a ventricular wall;

(e) forming a plurality of channels in the wall of the heart, for instance through the heart myocardium;

(f) maintaining a distal portion of the TMR energy delivery device against tissue of the wall through which the channel is to be formed while transmitting energy from a remote source through the TMR energy delivery device;

(g) urging a distal portion of the TMR energy delivery device against the heart wall while delivering energy through the TMR energy delivery device;

(h) delivering energy from the TMR energy delivery device through a gaseous medium to the heart wall;

(i) forming the channel through an epicardium into at least a portion of a myocardium;

(j) forming the channel through an epicardium, a myocardium and at least a portion of an endocardium;

(k) using as the TMR energy delivery device a laser wave guide configured to be coupled to a laser source;

(l) using as the TMR energy delivery device a mechanical cutter;

(m) using as the TMR energy delivery device an ultrasound device configured to be coupled to an ultrasound source;

(n) using as the TMR energy delivery device a

microwave device configured to be coupled to a microwave source;

(o) using as the TMR energy delivery device an RF electrode configured to be coupled to an RF source;

(p) using as the TMR energy delivery device a fluid jet device configured to be coupled to a fluid jet source;

(q) employing a first visualization device which is configured to be maneuvered and provide access to more than one region of a heart myocardium;

(r) employing a first visualization device which is an articulating scope;

(s) employing a first visualization device which is a rigid scope;

(t) forming a second minimally invasive penetration in the patient's chest; and introducing a tool through the second minimally invasive penetration; and

(u) forming a second minimally invasive penetration in the patient's chest; and introducing a second visualization device through the second minimally invasive penetration to view an interior of the patient's heart.

In another embodiment of the invention, A method of closed-chest formation of a channel in a wall of a heart includes forming first, second and third minimally invasive penetrations in a patient's chest. A first visualization device is introduced through the first minimally invasive penetration. The heart is prepared for channel formation by using tools introduced through the second and third minimally invasive penetrations. A second visualization device includes a working channel and is introduced through the third minimally invasive penetration. An energy delivery device is introduced through either the second minimally invasive penetration or the working channel of the second visualization device. Sufficient energy from the energy delivery device is delivered to the wall of the heart to form a channel through at least a portion of the wall.

In some embodiments, the second visualization device is an articulating scope.

In some embodiments, the first visualization device is configured to enable visualization of at least a portion of a left hemisphere of the heart.

The first visualization device may be configured to enable visualization of at least 50% of a heart surface that faces the first minimally invasive penetration.

The first visualization device may be configured to enable visualization of a coronary artery.

The first visualization device may be configured to enable visualization of one or more vessels and one or more coronary arteries in a selected line of fire of the TMR energy delivery device.

In some embodiments the TMR energy delivery device may be directed to different areas of the wall of the heart under direct visualization of the first visualization device.

Preferably, the second visualization device may provide visualization of at least a portion of an exterior of the heart.

The first visualization device may provide visualization of at least a portion of an exterior of the heart. Alternatively, the first and second visualization devices provide visualization of at least a portion of an exterior of the heart.

In certain embodiments, the second visualization device is configured to be maneuvered and provide access to more than one region of a heart myocardium.

In another embodiment, a TMR energy delivery system includes a reusable visualization member. A TMR energy delivery device is removably mounted to the reusable visualization member. The TMR energy delivery device includes a distal section and is configured to deliver a sufficient level of energy to create a channel in a heart wall.

The positioning of the visualization devices and the working tools can be interchanged between the first, second and third minimally invasively formed penetrations.

EP-A-0797958 concerns a unitary MIS device having an enlarged chamber at the distal tip with a transparent viewing surface between the camera or fibre optic viewing device and the tissue. The viewing mechanism is carried within the chamber, or a fibre optic viewing bundle is positioned within the chamber. The fibre optic TMR device is also advanced into the chamber and is extendable from the chamber through one or more apertures. A preferred embodiment of the present invention may make use of a bronchoscope to provide a visualisation member. This may be a modified, conventional bronchoscope with a working tool channel to take advantage of the optics. Thus the system may be a kit with disposables that can be used with a reusable scope. The modifications may include a handle linkage to allow single handed control of articulation of the scope from the attached TMR handle having the mechanism for advancing and retracting the fibre. Rigid attachment to the articulating portion of the conventional scope may allow gross positioning. Finally, the distal tip portion preferably does not include a sealed chamber, but rather utilizes a suction cup stabilizer, and stand-off mechanism, or a flange with openings for viewing with the scope and the working channel.

In a further aspect there is provided a method of closed-chest formation of a channel in a wall of a heart, comprising:

introducing a TMR energy delivery device through a

first minimally invasive penetration of a patient's chest;

using a first hand to control a global direction and a retraction of the TMR energy delivery device;

using a second hand to control an advancement of the TMR energy delivery device and an articulation of a distal portion of the TMR energy delivery device; and

activating the TMR energy delivery device to form a channel through at least a portion of the wall.

In preferred embodiments of this aspect the method further may comprise providing a table mounted scope holder to control movement of the TMR energy delivery device. Alternatively it may comprise providing a patient mounted scope holder to control movement of the TMR energy delivery device.

In a further aspect of the invention, there is provided a method of closed-chest formation of a channel in a wall of a heart, comprising:

introducing an articulating TMR fiber coupled to a scope through a minimally invasive penetration in a patient's chest to a posterior side of the heart, the scope including a distal portion, an articulating section and a rigid shaft proximal to the articulating section segment of the TMR fiber;

applying a contributing force with the rigid shaft to retract the heart; and

delivering sufficient energy to form a channel through at least a portion of the posterior side of the heart.

Suitably, the TMR fiber has an exposure length sufficient to enable an operator to provide an adjustment for differing bend radii. For instance, the scope includes a handle and the TMR fiber has an exposure length sufficient to enable an operator to provide an adjustment for differing bend radii by making an adjustment with an adjustment device coupled to the handle. An example of the adjustment device is a locking jam nut positioned on the handle.

In some embodiments, the TMR fiber optic is a multifiber bundle configured to facilitate ease of bending by a cable tensioning and deflection member.

In further embodiments, the TMR fiber optic is fully removable from the handle and configured to be introduced through a separate pneumo needle.

Embodiments of the invention are described below by way of example only, and with reference to the accompanying drawings of which:

Figure 1 is a perspective view of a patient illustrating first, second and third minimally invasive formed penetrations formed in the patient's chest and used to create REVASCULARIZATION channels, as well as the introduction of a pneumo needle.

Figure 2 is a perspective view of an interior of the patient's chest illustrated in Figure 1.

Figure 3 is a top and side perspective view of the rigid portion of an embodiments of articulating scope of the present invention.

Figure 4 is a side perspective view of the articulating scope of Figure 3.

Figure 5 is a top and first side perspective view of a mechanical linkage of the articulating scope of Figure 3.

Figure 6 is a top and second side perspective view of the mechanical linkage of the articulating scope of Figure 3.

Figure 7 is an exploded view of the articulating scope of Figure 3.

Figure 8 is a perspective view of the rigid and flexible portions of the articulating scope of Figure 3.

The present invention provides a method and apparatus for a closed-chest formation of a revascularization channel in a wall of a heart. An energy delivery device is introduced through a first minimally invasive penetration of a patient's chest. Sufficient energy is delivered from the energy delivery device to the wall of the heart to form a channel through at least a portion of the wall. One, two, three, or more minimally invasively formed penetrations are formed in the patient's chest. One or more visualization devices are used. Working tools are introduced through one of the penetrations to prepare the heart for the creation of revascularizations channels. The first visualization device can be a rigid scope which provides a desired viewing of most or all the exterior of the heart to identify larger coronary vessels, presence of pericardium, adhesions and the like. The second visualization device is preferably an articulating scope with a working channel which allows identification of smaller coronary vessels to be avoided during TMR. The functions of both scopes can be combined in the articulating scope. Revascularization channel formation can proceed with the energy delivery device being introduced through any of the first, second or third minimally invasively formed penetrations that are made.

For purposes of the present invention, a minimally invasively formed penetration means a penetration that is not large, does not involve opening the chest, spreading ribs and cutting through ribs and/or the sternum. Minimally invasive also includes the formation of penetrations that may be performed intercostally or non-intercostally and going inside out to create channels in the ventricle from the inside tissue of the endocardium. "Channels" refers to revascularization entries through the epicardium or myocardium and further includes

entries that extend (i) all the way through the endocardium from the epicardium; (ii) partially through the myocardium from the epicardium; (iii) stimulation zones; (iv) drug pockets; or (v) from the endocardium, fully or partially through the myocardium.

Referring now to Figure 1, a perspective view of a patient 10 is shown with first, second and third minimally invasively formed penetrations 12, 14 and 16 respectively. It will be appreciated that the exact location of penetrations 12, 14 and 16 is not limited to those illustrated in Figure 1. Additionally, from 1 to N+1 numbers of penetrations may be made.

The patient is prepared for the procedure and is positioned similarly to that used for a left thoracotomy. The patient's left arm is draped. A conventional double lumen endotracheal tube is used to selectively deflate one side or the other of the lungs. Preferably the left lung is collapsed which allows access to the chest cavity in the vicinity of the left lung. The other lung remains inflated to provide oxygenation.

In various embodiments of the present invention, a distal portion of the energy delivery device is positioned to reach a desired aspect of a ventricular wall. A plurality of different revascularization channels are formed in the heart. A distal portion of the energy delivery device can be positioned against tissue of the wall of the heart through which the channel is to be formed while transmitting energy from a remote energy source through the energy delivery device. Suitable energy delivery devices include but are not limited to laser wave guides, RF electrodes, microwave cutters, ultrasound transmitters, mechanical coring devices, fluid jets and the like. Each energy delivery device is configured to be coupled to an energy source including but not limited to RF, laser, microwave, ultrasound, mechanical coring, fluid jet, cryogenic fluid, chemical ablation and the like. The distal portion of the energy delivery device can be urged against the heart wall while energy is delivered through the energy delivery device. Additionally, instead of the energy delivery device making physical contact with the heart wall the energy delivery device can deliver energy through a gaseous medium to the heart wall Additionally, the waveguide may be configured to pierce the epicardium so that energy is delivered to the myocardium. A revascularization channel can be formed through an epicardium into at least a portion of a myocardium or continue through the myocardium into all or only a portion of the endocardium.

In one embodiment, penetration 12 is used for the introduction of a rigid scope which can be, for example, a standard 10 mm laparoscope or thorascope. A suitable rigid scope is available from STRYKER, WOLF, or STORZ. The rigid scope provides a global view of an internal chest area of interest. For standard TMR at the apex region of the heart, a first penetration 12 can be from the fourth to sixth intercostal space and may be 10 to 12 mm in diameter. A slight cut-down is made and a standard thoracic trocar is advanced through the chest. A rigid scope typically found in an operating room is then inserted. Commonly available rigid scopes can be zero to 60 degree scopes such as the STORZ 26003AA 0° 10mm x 3/cm scope, or STORZ 26003BA 30°, 10mm x 3/cm. Other rigid or articulating scopes are also suitable.

A 30 degree rigid scope may be used for a narrow chest cavity because there a limited amount of chest cavity space is available. Additionally, the 30 degree scope permits bending. Choice of rigid scope is a surgical preference by the practitioner.

The rigid scope is used to visualize the area, look for larger coronary vessels, to inspect the condition of the pericardium, and to check for adhesions. The shape of the heart as well as its position is visualized. Second penetration 14 is formed inferior to penetration 12 and can be formed just above the diaphragm and third penetration 16 is formed superior to penetration 12. Penetrations 14 and 16 can be formed substantially the same way as penetration 12 is formed or may be cut downs only.

For initial procedures a pair of thorascopic graspers may be introduced through penetration 14. Additional tools that can be introduced through penetration 14 include scissors. The pericardial sac 18 (Figure 2), if intact, is grabbed and opened up by making a stem to stern type of incision. The pericardial sac is pulled away from the heart and may be suspended. Any unwanted adhesions are removed.

After the tools are removed from penetration 14, an articulating scope, with working channel, is introduced. A suitable articulating scope is a bronchoscope. The articulating scope may be a digital scope where the CCD portion is at the far end so it does not require additional optics throughout the length of the scope. This provides a camera at the articulating scope's tip. When the functionality of the rigid scope is incorporated into the articulating scope then the need for the rigid scope is then eliminated. Additionally, the articulating scope can be inserted in the first penetration and the rigid scope can be inserted into second penetration 14 after the tools are removed from second penetration 14. The articulating scope generally provides a view sufficient to visualize and avoid small coronary arteries.

Third penetration 16 is formed, a trocar introduced and a pair of forceps places an absorbing medium, including but not limited to a piece of gauze through the third penetration 16. Third penetration 16 is created initially to open the pericardial sac and subsequently may be used as a treatment port, for visualization or for safety reasons. In the event that a structure, such as a coronary artery is nicked and bleeding is initiated, direct pressure is applied by placing the gauze on the area through third penetration 16 to stop the bleeding. The gauze is also useful for manipulating the heart and applying slight pressure to TMR entrance sites to avoid excessive bleeding.

In one embodiment, articulating scope is initially

positioned in penetration 14 and revascularization channels are created at the desired location, such as the apex 20. Preferably the energy delivery device is inserted through the working channel of the articulating scope adapted for the procedure. The articulating scope also may be initially positioned in penetration 12 or 16. Once the desired number of revascularization channels is formed, the articulating scope is removed. Graspers and needle holders, or other instruments, are introduced through one of the penetrations to stitch back the pericardial sac, if necessary. A check is made to ensure that there is no bleeding, trocars are removed and the penetrations closed. It will be recognized that the procedure will vary, depending upon the condition of the heart and the site of the procedure.

Referring now to Figure 3, an articulating scope 22 suitable for use with the present invention is illustrated. In one embodiment, articulating scope 22 includes a flexible distal portion which provides for a coupling of a surface of the heart to the distal portion of articulating scope 22 to provide for the stability of the apparatus on the beating heart. Articulating scope 22 has an articulating distal portion that is coupled to a control member 24 to provide articulation. Articulation can be by a mechanical force, via electronic motion, and the like. Control member 24 can include a straightening device that is coupled to a pre-bent shaft of articulating scope. Movement of control member 24 causes deflection, including articulation, of the generally flexible working end of the scope in a manner well known in the art. Articulating scope 22 may also include a vacuum port 26 configured to be coupled to a vacuum source. The coupler may be a two way valve to provide both vacuum and flushing solutions. Application of a vacuum couples the distal portion of articulating scope 22 to the heart. Other methods of coupling include but are not limited to use of a piercing tip to anchor to the epicardium or by providing a patterned, textured gripping surface at the distal tip. Articulating scope 22 can be supported by a scope holder that is table mounted or mounted to the patient.

An access port 27 is provided for the introduction of tools and instruments including but not limited to scissors, graspers, fiber optic tools, suture mechanisms. An adaptor 28, including but not limited to rigid or articulating couplers/fittings extending at any angle to the longitudinal axis of scope 22, couples access port 27 with a handle 30. Handle 30 is configured to move in an up and down fashion and provides a working channel for the introduction of an energy delivery device. The coupling of adaptor 28 to articulating scope can be achieved in different ways, however, in one embodiment, a ball joint socket 32 is employed to allow movement of the handle 30. A standard scope holder (not shown) and adapter can be used to cradle and stabilize articulating scope 22 and attaches along a surface 34 of articulating scope 22 and to the operative table. Additionally, a similar standard scope holder can also be used to cradle the rigid scope. Coupled to handle 30 is an energy delivery device retention member 33. An energy delivery device advancement member 35 is actuated by the thumb and advances and retracts an energy delivery device 36 through articulating scope 22 to and from a selected site. A proximal portion of retention member 33 is a compression fitting that can lock energy delivery device 36 in position so that its advancement//retraction distances are controlled solely by member 35. Retention member includes a thumb activated knob which may be tightened and loosened.

Control member 24 moves in connection with the motion of handle 30. Control member 24 provides the desired degree of deflection at the distal portion of articulating scope 22. The physician's hand is on handle 20 which thus controls member 24. Sufficient friction is provided to retain energy delivery device 36 at its desired location without the physician having to move his/her finger or thumb to control member 24.

Handle 30 also provides for easy deflection/positioning of the flexible distal tip of scope 22. Once a desired site is selected, the physician's hand remains on handle 30 and with wrist motion moving joint socket 32 can provide multiple movements of the distal tip of the scope 22 bearing the energy delivery device 36. The physician's other hand remains on a rigid or semi-rigid section 38, which in one embodiment is a cable, (see Fig. 8) of the distal portion of articulating scope 22 that is associated with a flexible portion of articulating scope 22 to provide gross placement of the tip of the scope movement. This provides single hand movement of energy delivery device 36. The physician's hand on handle 30 articulates the distal portion of articulating scope 22 and advances the physician's finger on member 35 and retracts energy delivery device 36.

One embodiment of articulating scope 22 is shown in Figure 4 with a mechanical linkage 40 to provide single handed placement and advancement/retraction of waveguide 36. A ball joint is replaced with a knuckle joint 42 to allow handle 30 to be moved in an up and down motion. Mechanical linkage 40 is coupled to control member 24. A friction imparting device 42, including but not limited to a friction plate, is included as a separate element. Alternatively, the function of providing friction can be included in knuckle joint 42 and included as part of mechanical linkage 40 to control member 24.

Figures 5 and 6 illustrate different perspective view of articulating scope 22. Figure 7 is an exploded view of articulating scope 22 and includes a cover 44 which covers mechanical linkage 40. As can be seen, the linkage allows the physician to move the position of the distal tip of the scope on the heart to create additional channels without removing his hand from the handle which controls energy delivery device 36.

Referring now to Figure 8, a strain relief member 46 couples a flexible portion, generally denoted as 48 to a rigid portion 50 of articulating scope 22. A flexible tubular member 52 carries energy delivery device 36 and is

coupled to rigid or semi rigid member 38 with a second strain relief member 54. Strain relief member 54 may be a compression fitting. Rigid member 38 provides steerability and stability for accurate placement of energy delivery device 36 as it is advanced. Rigid member 38 also minimizes rotation and axial movement.

Coupled to a distal end of rigid member 38 is a flexible member 56 which maintains flexibility at the distal tip. A silicon rubber, plastic material, elastomer, or other flexible member permits maximum articulation of energy delivery device 36 when control member 24 is activated. Flexible member 56 is generally very thin silicon rubber or flexible plastic in order to continue to provide articulation and good movement of energy delivery device 36. The thinness of flexible member 56 permits full or near full articulation of energy delivery device 36. If flexible member 56 is too thick, then articulation may be sacrificed. Additionally, the distal tip of flexible member 56 is configured to hold off the optics of articulating scope 22 from the surface of the heart in order to help maintain a specified field of view and maintain focus. Flexible member 56 assists in keeping the optics in focus, reduces smudging of the optics, and allows access to substantially all walls of the heart (lateral anterior and posterior). Flexible member 56 is preferably made of a material that permits the passage of ambient light which provides enhanced viewing.

In one embodiment, a cup member 58 is coupled to a distal end of flexible member 56. Cup member 58 is coupled to a vacuum source and becomes attached to a wall of the heart. Cup member 58 provides a broad surface which becomes locked on the wall of the heart. While the heart is beating the ability of locking articulating scope 22 via cup member 56 and the use of a vacuum source provides mechanical stability when energy is delivered from an energy source through energy delivery device 36 to a selected target site. Cup member 58 helps to keep the optics clean and provides a protective shield if the distal end of energy delivery device 36 has a piercing point which can scratch the heart.

In other embodiments, cup member 58 is replaced with a flange with a gripping surface that provides the locking function.

In various embodiments, the trocar introduced in any of penetrations 12, 14 or 16 can be an introducer made of TEFLON, polypropane, and the like. Slits may be formed in the introducer to permit cup member 58 to be easily retracted into an interior lumen of the trocar. It will be understood by those skilled in the art that the procedures described above are examples only. For instance, the control of the articulating scope need not be coupled to control fiber advancement or fiber advancement may be controlled from the scope. Additionally, any number of introducer devices may be inserted as needed.

The foregoing description of a preferred embodiment of the invention has been presented for purposes of illustration and description. It is not intended to be exhaustive or to limit the invention to the precise forms disclosed. Obviously, many modifications and variations will be apparent to practitioners skilled in this art. It is intended that the scope of the invention be defined by the following claims and their equivalents.

Claims

1. A TMR energy delivery system, comprising:

   a reusable visualization member; and
   a TMR energy delivery device removably mounted to the reusable visualization member and configured to deliver a sufficient level of energy to create a channel in a heart wall, wherein the TMR energy delivery device includes a distal section.

2. The system of claim 1, wherein the visualization member is a fiber optic.

3. The system of claim I, wherein the visualization member is a CCD based camera system.

4. The system of claim 3, wherein the camera is disposable.

5. The system of claim 3, wherein the camera is reusable.

6. The system of claim 3, wherein the camera is usable for a selected number of uses.

7. The system of any one of the preceding claims, wherein the TMR energy delivery device includes a handle with at least one of an axially or rotationally moving member configured to facilitate movement of an optical fiber, wherein the optical fiber delivers laser energy to a selected site and a cable coupling the distal portion of the TMR energy delivery device to the handle.

8. The system of any one of claims 1 to 6, wherein the TMR energy delivery device includes a handle with an optical fiber advancement member and a hand actuated motion device configured to provide an articulation of a distal portion of the optical fiber.

9. The system of claim 8, wherein the articulation motion is provided by any of: a cable member; a linkage member; a pressure member; a mechanical force member; or an electronic member.

10. The system of claim 7, further comprising: a stiffener member providing an increased rigidity of the cable.

11. The system of claim 10, further comprising: a stand-off member coupled to a flexible portion of the distal portion of the TMR energy delivery device, wherein the stand-off member is configured to improve visualization.

12. The system of claim 11, wherein the stand-off member is configured to provide an anchoring of a distal end of the TMR energy delivery device.

13. The system of claim 11 or 12, wherein the stand-off member includes a suction cup.

14. The system of claim 11 or 12, wherein the stand-off device includes a lubricious exterior surface.

15. The system of any one of claims 11 to 14, wherein the stand-off device and the handle are incorporated as a single unit.

16. The system of any one of claims 11 to 14, wherein the stand-off device and the handle are separate units.

17. The system of any one of claims 11 to 16, wherein the stand-off device is coupled to the visualization device with an elastomer.

18. The system of any one of claims 11 to 16, wherein the stand-off device is coupled to the visualization device with a mechanically adjustable collar that provides compression.

19. A TMR delivery system, comprising:

A TMR energy delivery device including an elongated body;
a camera configured to provide a minimally invasive surgical site view, the camera including a shaft with at least a portion of the shaft being flexible; and
an articulation device coupled to one of the TMR energy delivery device or the camera and providing a simultaneous straightening and articulation of at least a portion of the camera and at least a portion of the TMR energy delivery device following introducing of the TMR energy delivery device and the camera through a trocar port.

20. The system of claim 19, wherein the articulation device includes a pull cable.

21. The system of claim 19, wherein the articulation device includes a straightening device configured to be coupled to a pre-bent shaft of the elongated body.

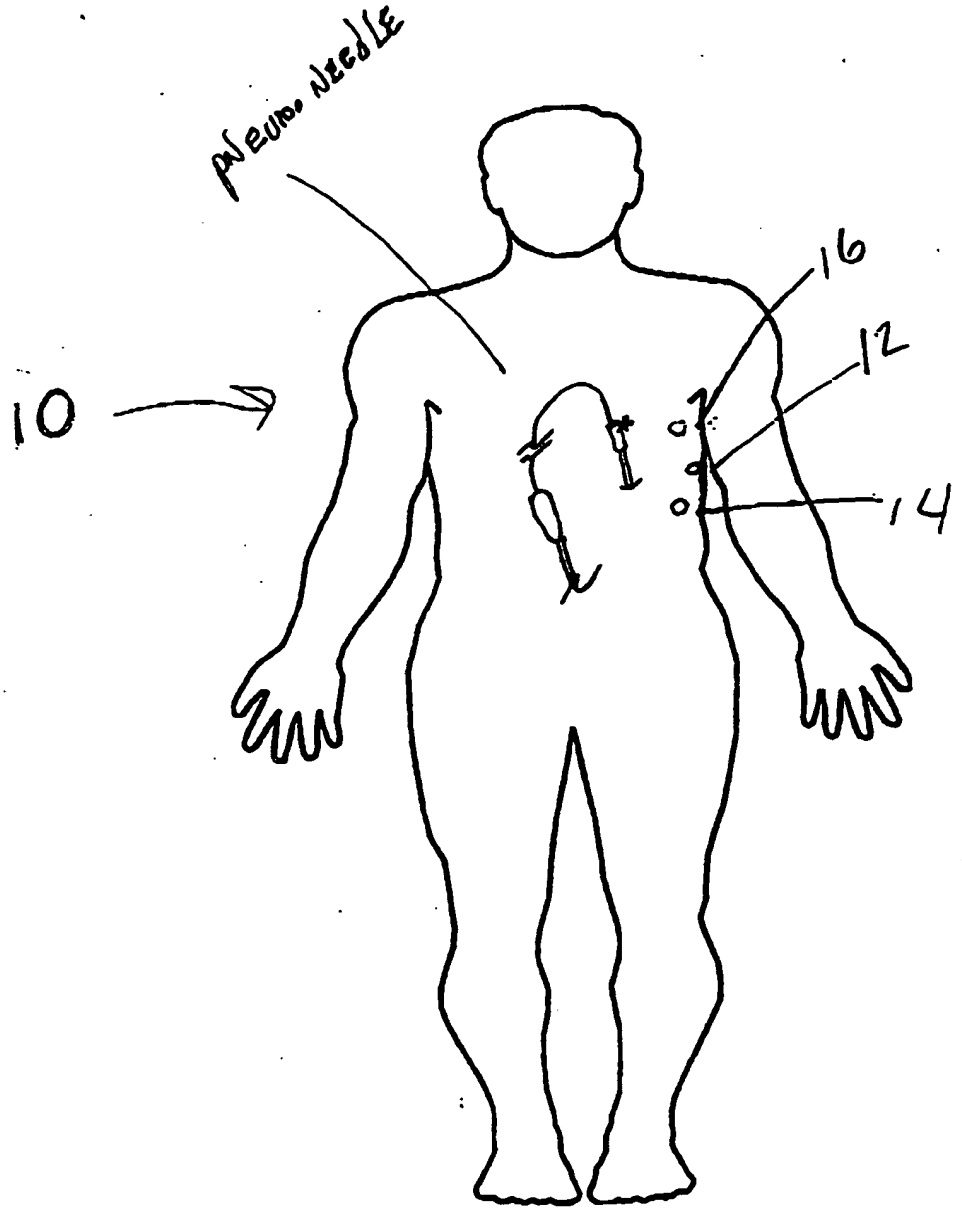

Figure 1

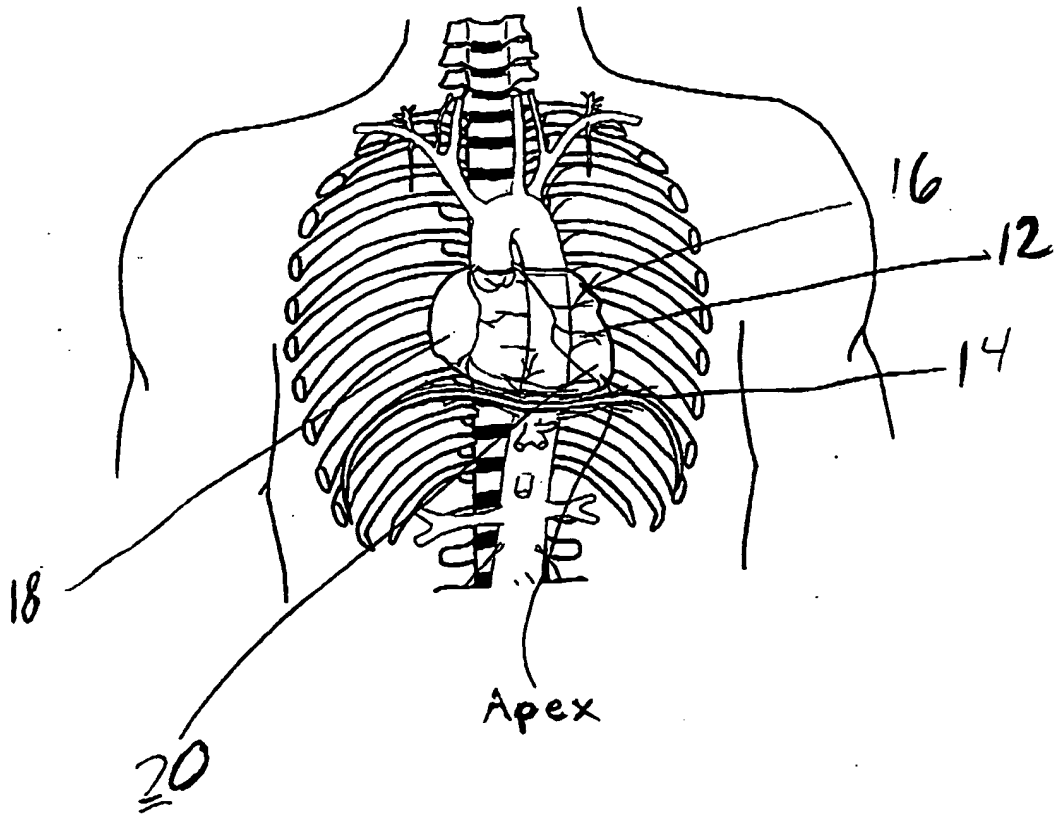

Figure 2

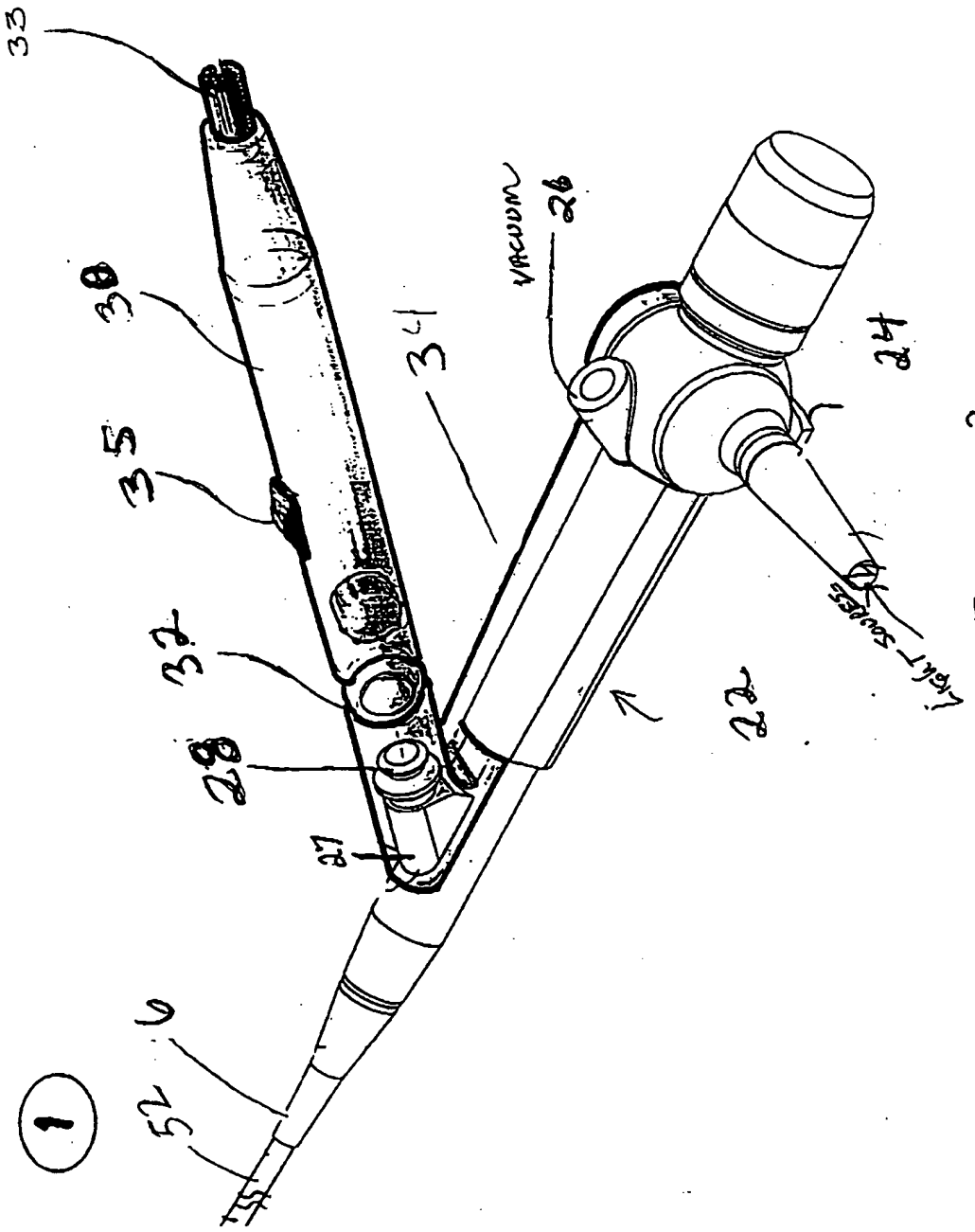

Figure 3

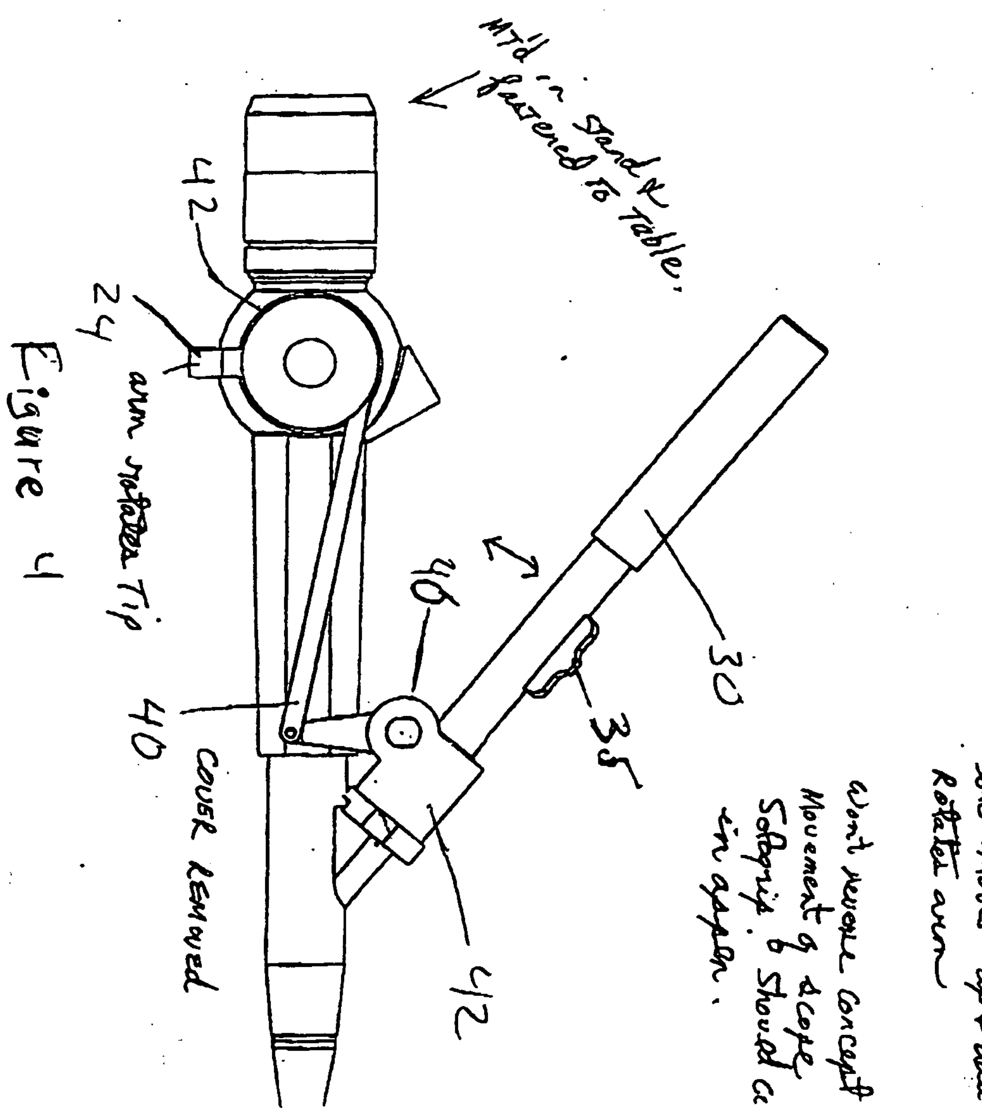
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Figure 4

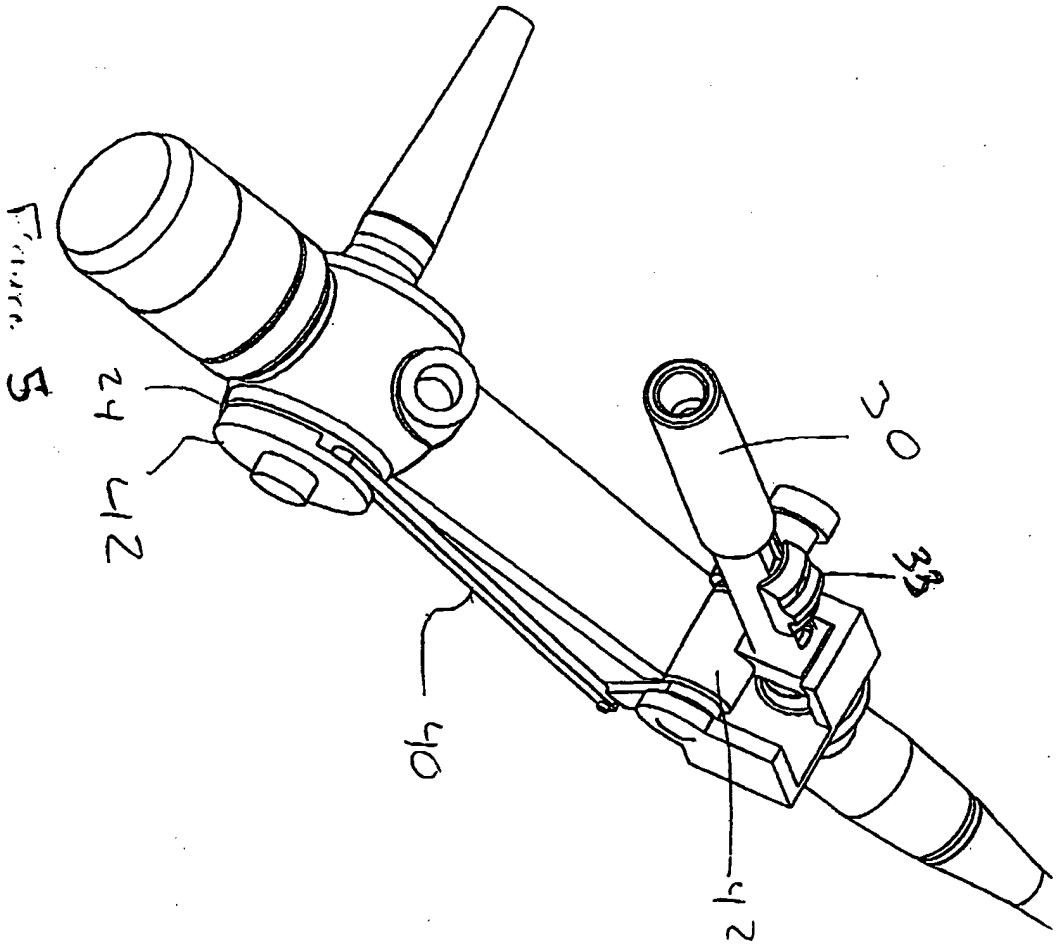
Fig. 5
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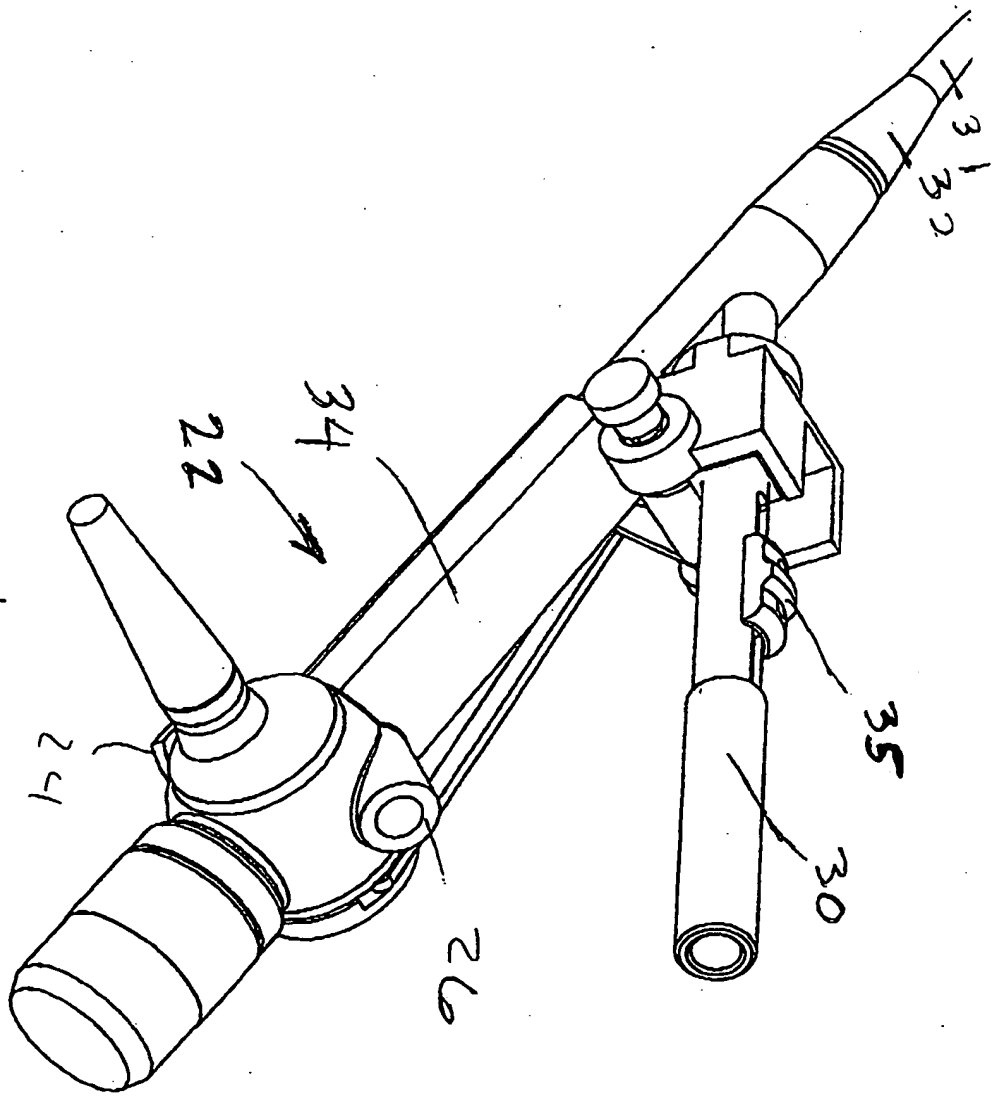

Fig 6

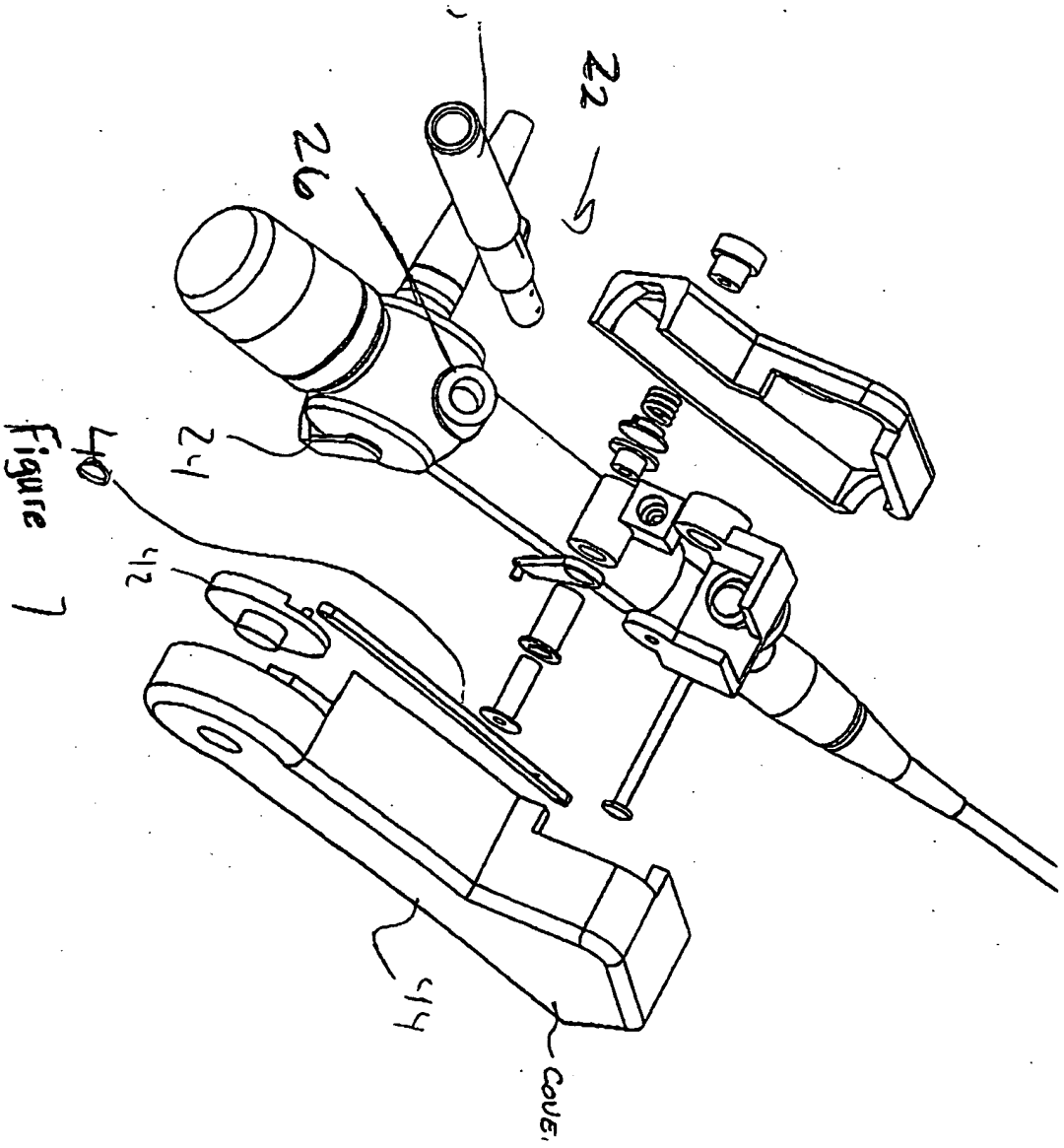

Figure 1

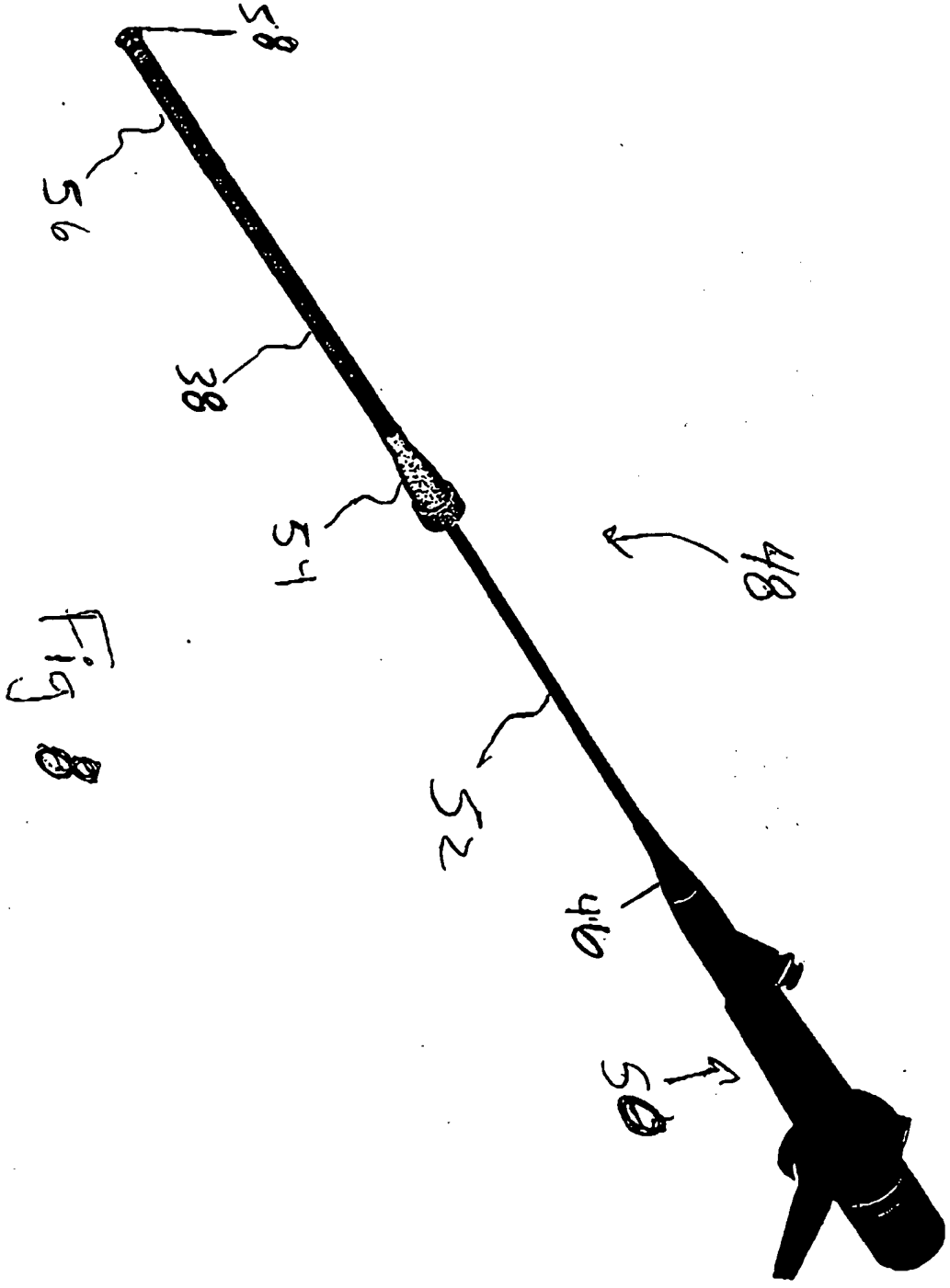

Fig. 8

European Patent Office

EUROPEAN SEARCH REPORT

Application Number

DOCUMENTS CONSIDERED TO BE RELEVANT

EP 98300728.7

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl. 6)
D,Y	US 5389096 A (AITA) 14 February 1995 (14.02.95), the whole document. --	1-21	A 61 B 17/36
Y	US 4072147 A (HETT) 07 February 1978 (07.02.78), the whole document. --	1-21	
Y	WO 93/20742 A1 (DANEK) 28 October 1993 (28.10.93), the whole document. ----	1-21	

TECHNICAL FIELDS SEARCHED (Int. Cl. 6)

A 61 B
A 61 N

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
VIENNA	30-04-1998	NARDAI

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
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